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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>23 December 2008</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-28</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-28</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of Claims

1.   In the amendment filed 12/23/2008, the following occurred: claims 1, 15, and 18

were amended. Claims 1-28 are presented for examination.

Response to Amendments

2.   Applicant's amendments to claim 15 succeed in overcoming the pervious 35

U.S.C. 112, second paragraph, indefinite rejections.

3.   The amendments to claims 1, 15, and 18 appear to not add new matter and will

be treated below on the merits.

Claim Rejections - 35 USC § 102

4.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5.   **Claims 1-9, 11, 13-21, and 23-25** are rejected under 35 U.S.C. 102(e) as being

anticipated by U.S. Patent Application Publication 2002/0038392 to De La Huerga.

6.   As per claim 1, De La Huerga teaches a healthcare system for a care-giving

facility, comprising:

        --*a medical device* (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and

108d)(see: De La Huerga, paragraphs 187, is met by IV pumps);

   --*a user interface* (Fig. 17, ele. 106 and 123)(see: De La Huerga, paragraph 145,

is met by display, keyboard, and mouse);

   --*a first central computer having a first database* (Fig. 17, ele 103, 104, and 105;

and Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 145, 151, and 152, is

met by infusion controller, its processor and memory) *and a first functional feature set*

associated with the data and functions related to the medical device and the user

interface (Fig. 18)(see: De La Huerga, paragraph 151, 152, and 167, is met by delivery

parameters), *wherein the medical device and user interface communicate directly with*

first central computer (see: De La Huerga, paragraph 145, 146, 147, and 149);

   --*a second central computer having a second database* (Fig. 26, ele. 260; and

Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met

by controller and memory) *and a second functional feature set* (see: De La Huerga,

paragraphs 211, 243, is met by alert activator, and indicator activation), *wherein the first*

central computer is securely connected to the second computer (Fig. 26, ele. 255a and

255b)(see: De La Huerga, paragraph 149, 195, and 273, is met by the various

networks), *wherein the medical device and the user interface do not communicate*

directly with the second central computer (Fig. 17, ele. 100, 104, 123, 124, and 255; and

Fig. 26, ele. 100a, 255a, and 260, is met by configuration of the controller, infusion

controller, and the interface)(see: De La Huerga, paragraph 149, 151, and 211, is met

by the controller activating an indicator via the infusion controller); *and*

   --*wherein the user interface can receive data from the second database relating*

to the second functional feature set of the second central computer through the first

central computer (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and

260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149, 151, and 211, is met

by the controller activating an indicator via the infusion controller).

De La Huerga also teaches: <u>wherein the first database is a subset of the second</u>

<u>database,</u> (see: De La Huerga, paragraph 243, is met by server that archives all

standing infusion orders).

7.   As per claim 2, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the first functional feature set comprises at least one of a volumetric infusion

pump feature (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and 108d)(see: De

La Huerga, paragraphs 187, is met by IV pumps), *and a syringe pump feature* (see: De

La Huerga, paragraph 330, is met by syringe injectors).

8.   As per claim 3, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the first functional feature set comprises at least one of a change pump channel

feature, an administer infusion feature, a stop or discontinue infusion feature (Fig.

18)(see: De La Huerga, paragraph 150-152, 167, 173, 208, 210, 279, and 322, is met

by delivery parameters adjustment, including duration, and "OFF" and "discontinue"

options; and "stop and start" buttons), *a resume infusion feature, and a remove pump*

feature.

9.   As per claim 4, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--*the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature, an alarms/alerts feature* (see: De La Huerga, paragraphs 211, 243, is met by alert activator, and indicator activation), *a billing interface feature, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature.*

10.   As per claim 5, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

--*the first database comprises at least one of pump data* (Fig. 18)(see: De La Huerga, paragraph 151, 152, 167, 208, 210, 273, and 322, is met by delivery parameters), *pump channel data, pump sub-channel data, order data, clinician data, patient data, user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data.*

11.   As per claim 6, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

--*the second database comprises at least one of patient management data* (Fig. 26, ele. 260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by memory with stored patient ID), *item management data, facility management*

data, messaging data, alarms/alerts data, inventory tracking data, a clinician

administration data, order entry data, user interface and clinician association data.

12.   As per claim 7, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the first central computer is operably connected to the second computer

through at least one of a dedicated TCP/IP hard-wired connection, a high speed, low

latency virtual private network, and a public or shared infrastructure utilizing encryption

through a fiber optic connection, a microware connection, or a high speed wireless

connection (Fig. 26, ele. 100a, 100b, 255a, 255b, and 260)(see: De La Huerga,

paragraphs 149, 194, 195, and 273, is met by wireless connections).

13.   As per claim 8, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the second central computer sends data from the second database to the first

central computer in a first standard protocol, and the first central computer sends the

data to the user interface in a second standard protocol (Fig. 17, ele. 104, 123, 124, and

255; Fig. 26, ele. 100a, 255a, and 260; and Fig. 26A, ele. 622)(see: De La Huerga,

paragraphs 145-151, 194, 195, and 211, the first protocol is met by communication

between the interface and the first computer, and the second protocol is met by the

plurality of protocols including: an Internet protocol, Bluetooth protocol, and IRDA

protocol).

14.   As per claim 9, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database with the second data, and wherein the first central computer sends the combined fist and second data to the user interface for display on a display of the user interface (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and 260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149-151, 211, 285, and 289-291, is met by additional patient information obtained from remote facility server and displayed on interface screen; is met by the controller activating an indicator, or alert displaying patent's name, on the interface via the infusion controller; and is met by altering infusion status parameters displayed on the user interface with data entered at the controller or infusion controller).

15.   As per claim 11, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives second data from the second database in the second central computer for use in a validation procedure (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller).

16.   As per claim 13, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives data from at least one of the user interface (see: De La Huerga, paragraph 290, is met by change of dose via the interface keypad) *and the medical device,*

--and determines whether the received data is valid in order to enable the first

central computer to perform a further step (see: De La Huerga, paragraph 159 and 290,

is met by changes to delivery instructions using the interface allowed if verified by the

infusion controller as acceptable).

17.   As per claim 14, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--the first central computer sends operation data from at least one of the first

database and the second database to the medical device for use in the operation of the

medical device (see: De La Huerga, paragraph 149-151, is met by the infusion

controller controlling the pump to infuse medications).

18.   As per claim 15, De La Huerga teaches a method for operating a healthcare

system in a care-giving facility having a medical device, a user interface, a first central

computer securely connected to a second central computer having a second database,

the method comprising the steps of:

--receiving medical data directly from a medical device (Fig. 26, ele. 830)(see: De

La Huerga, paragraph 295 and 296, is met by monitoring device);

--receiving user data directly from a user interface (Fig. 26, ele. 264 and

266)(see: De La Huerga, paragraph 192, 193, 201, 207, 208, and 209, is met by

interface including keyboard for to receive input from a controller user);

--receiving second data from a second database in a second central computer

(Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraph 259, 260, 271, and 320, is

met by the server and its database from which data is provided to the receiving

controller) *and from a secure connection* (Fig. 26, ele. 272; and Fig. 31, ele., 272)(see: De La Huerga, paragraph 89, 194, 195, 291, 300, and 320, is met by the network and network protocols);

--*retrieving first data from a first database in a first central computer* (Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraph 192, 199, 200-206, is met by controller memory storing patient and pump information, and associated processor able to retrieve and send to the interface the stored information); *and,*

--*utilizing a first functional feature set to process at least one of the first data and the second data* (see: De La Huerga, paragraph 259-260, 269-271, and 320, is met by the controller upon receiving a prescription order accessing remaining components on dispensed medication information, via a network, from a hospital computer system and database).

De La Huerga also teaches that the first database: *is a subset of the second database,* (see: De La Huerga, paragraph 243, is met by server that archives all standing infusion orders).

19.   As per claim 16, De La Huerga teaches the invention as claimed, see discussion of claim 15, and further teaches:

--*the medical device and the user interface do not communicate directly with the second central computer* (Fig. 26, ele. 630, 632, 272, and 260; and Fig. 26, ele. 830, 255c, 260, 270, and 272, is met by configuration of the controller, medical device, the interface, and the database and server)(see: De La Huerga, paragraph 259-260, 269-271, 295, 296, and 320).

20.   As per claim 17, De La Huerga teaches the invention as claimed, see discussion

of claim 15, and further teaches:

--*providing for sending the second data to the user interface from the first central*

computer (Fig. 26, ele. 630, 632, 272, and 260; and Fig. 26, ele. 830, 255c, 260, 270,

and 272, is met by configuration of the controller, medical device, the interface, and the

database and server)(see: De La Huerga, paragraph 259-260, 269-271, 295, 296, and

320, is met by the controller upon receiving a prescription order accessing with the

controller interface the remaining components on dispensed medication information, via

a network, from a hospital computer system and database).

21.   As per claim 18, De La Huerga teaches a healthcare system for a care-giving

facility, comprising:

--*a medical device* (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and

108d)(see: De La Huerga, paragraphs 187, is met by IV pumps);

--*a user interface* (Fig. 17, ele. 106 and 123)(see: De La Huerga, paragraph 145,

is met by display, keyboard, and mouse);

--*a central validation computer having a validation database* (Fig. 17, ele 103,

104, and 105; and Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 145,

151, and 152, is met by infusion controller, its processor and memory) *and a first*

functional feature set associated with the data and functions related to the medical

device and the user interface (Fig. 18)(see: De La Huerga, paragraph 151, 152, and

167, is met by delivery parameters), *wherein the medical device and user interface*

communicate directly and securely with the central validation computer (see: De La

Huerga, paragraph 145, 146, 147, and 149);

    --a second central computer having a second database (Fig. 26, ele. 260; and

Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met

by controller and memory) *and a second functional feature set* (see: De La Huerga,

paragraphs 211, 243, is met by alert activator, and indicator activation), *wherein the*

user interface can receive data from the second database relating to the second

functional feature set of the second central computer through the central validation

computer (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and 260; and

Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149, 151, and 211, is met by the

controller activating an indicator via the infusion controller).

    De La Huerga also teaches: <u>*wherein the validation database is a subset of the*</u>

<u>*second database,*</u> (see: De La Huerga, paragraph 243, is met by server that archives all

standing infusion orders).

22.   As per claim 19, De La Huerga teaches the invention as claimed, see discussion

of claim 18, and further teaches:

    --the central validation computer is securely connected to the second computer

computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 149, 195, and

273, is met by the various networks).

23.   As per claim 20, De La Huerga teaches the invention as claimed, see discussion

of claim 18, and further teaches:

--*the medical device and the user interface do not communicate directly with the second central computer* (Fig. 17, ele. 100, 104, 123, 124, and 255; and Fig. 26, ele. 100a, 255a, and 260, is met by configuration of the controller, infusion controller, and the interface)(see: De La Huerga, paragraph 149, 151, and 211, is met by the controller activating an indicator via the infusion controller).

24.   As per claim 21, De La Huerga teaches the invention as claimed, see discussion of claim 18, and further teaches:

--*the central validation computer receives second data from the second database in the second central computer for use in a validation procedure performed by the central validation computer* (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller).

25.   As per claim 23, De La Huerga teaches the invention as claimed, see discussion of claim 21, and further teaches:

--*central validation computer receives first data from at least one of the user interface* (see: De La Huerga, paragraph 290, is met by manual change dose via the interface keypad) *and the medical device, and*

--*wherein the validation procedure comprises the step of determining whether the first data matches the second data* (see: De La Huerga, paragraph 159 and 290, is met by changes to delivery instructions using the interface allowed if verified by the infusion controller as acceptable).

26.   As per claim 24, De La Huerga teaches a healthcare system for a care-giving

facility, comprising:

--*a medical device* (Fig. 26, ele. 100a, 100b, and 830)(see: De La Huerga,

paragraph 295 and 296, is met by monitoring device and pumps);

--*a user interface* (Fig. 26, ele. 264 and 266)(see: De La Huerga, paragraph 192,

193, 201, 207, 208, and 209, is met by interface including keyboard for to receive input

from a controller user);

--*a central validation portion of a central computer having a validation portion of a*

database (Fig. 26)(see: De La Huerga, paragraph 200-206, 210, 273, and 296, is met

by network validation protocols such as Bluetooth among others, and further validates

through polling, pump and controller address checks, and ID checks) *and a first*

functional feature set associated with the data and functions related to the medical

device and the user interface (Fig. 26)(see: De La Huerga, paragraph 200-211, 273,

and 296, is met by controller checking medical monitors and pump status checks, and

altering delivery parameters), *wherein the medical device and user interface*

communicate directly and securely with the central validation portion of the central

computer (Fig. 26, ele. 272; Fig. 26A; and Fig. 31, ele., 272)(see: De La Huerga,

paragraph 89, 192, 194, 195, 291, 300, and 320, is met by the network and network

protocols, and the controller interface being linked to the processor and memory);

--*a second non-validation portion of the central computer having a second non-*

validation portion of the database and a second functional feature set (Fig. 31, ele. 630

and 632)(see: De La Huerga, paragraph 259, 260, 271, and 320, is met by the server

and its database from which data is provided to the receiving controller), *wherein the*

user interface can receive data from the second non-validation portion of the database

relating to the second functional feature set of the second non-validation portion of the

central computer through the central validation portion of the central computer (see: De

La Huerga, paragraph 259-260, 269-271, and 320, is met by the controller upon

receiving a prescription order accessing remaining components on dispensed

medication information, via a network, from a hospital computer system and database).

27.   As per claim 25, De La Huerga teaches the invention as claimed, see discussion

of claim 24, but fails to specifically teach:

--the central validated portion of the central computer operates in a first

environment running a first operating system, and the second non-validation portion of

the central computer operates in a second environment running a second operating

system (see: Fig. 26, ele. 260; and Fig. 31, ele. 630)(see: De La Huerga, paragraph

192, 193, 259, 260, and 271, is met by the controller and server operating in their own

environments).

Claim Rejections - 35 USC § 103

28.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

29.   **Claims 1-9, 11, 13-21, and 23** are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga

in view of U.S. Patent Application Publication 2003/0084024 to Christensen.

30.   As per claim 1, De La Huerga teaches a healthcare system for a care-giving

facility, comprising:

--*a medical device* (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and

108d)(see: De La Huerga, paragraphs 187, is met by IV pumps);

--*a user interface* (Fig. 17, ele. 106 and 123)(see: De La Huerga, paragraph 145,

is met by display, keyboard, and mouse);

--*a first central computer having a first database* (Fig. 17, ele 103, 104, and 105;

and Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 145, 151, and 152, is

met by infusion controller, its processor and memory) *and a first functional feature set*

associated with the data and functions related to the medical device and the user

interface (Fig. 18)(see: De La Huerga, paragraph 151, 152, and 167, is met by delivery

parameters), *wherein the medical device and user interface communicate directly with*

first central computer (see: De La Huerga, paragraph 145, 146, 147, and 149);

--*a second central computer having a second database* (Fig. 26, ele. 260; and

Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met

by controller and memory) *and a second functional feature set* (see: De La Huerga,

paragraphs 211, 243, is met by alert activator, and indicator activation), *wherein the first*

central computer is securely connected to the second computer (Fig. 26, ele. 255a and

255b)(see: De La Huerga, paragraph 149, 195, and 273, is met by the various

networks), *wherein the medical device and the user interface do not communicate*

directly with the second central computer (Fig. 17, ele. 100, 104, 123, 124, and 255; and

Fig. 26, ele. 100a, 255a, and 260, is met by configuration of the controller, infusion

controller, and the interface)(see: De La Huerga, paragraph 149, 151, and 211, is met

by the controller activating an indicator via the infusion controller); *and*

--*wherein the user interface can receive data from the second database relating*

to the second functional feature set of the second central computer through the first

central computer (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and

260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149, 151, and 211, is met

by the controller activating an indicator via the infusion controller).

It had been shown above that De La Huerga also teaches: <u>wherein the first</u>

<u>database is a subset of the second database,</u> (see: De La Huerga, paragraph 243, is

met by server that archives all standing infusion orders); however, addressing the

alternative situation in which De La Huerga does not teach: <u>wherein the first database is</u>

<u>a subset of the second database,</u> Christensen teaches a first and second database that

are able to work in a coordinated manner in which the second database reflects or

contains the same information as the first database (see: Christensen, paragraph 61). It

would have been obvious to one of ordinary skill in the art at the time the invention was

made to combine the teachings of De La Huerga and Christensen. The well known

elements described are merely a combination of old elements, and in the combination,

each element merely would have performed the same function as it did separately, and

one of ordinary skill in the art would have recognized that the results of the combination

were predictable.

31.   As per claim 2, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

    --*the first functional feature set comprises at least one of a volumetric infusion*

pump feature (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and 108d)(see: De

La Huerga, paragraphs 187, is met by IV pumps), *and a syringe pump feature* (see: De

La Huerga, paragraph 330, is met by syringe injectors).

32.   As per claim 3, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

    --*the first functional feature set comprises at least one of a change pump channel*

feature, an administer infusion feature, a stop or discontinue infusion feature (Fig.

18)(see: De La Huerga, paragraph 150-152, 167, 173, 208, 210, 279, and 322, is met

by delivery parameters adjustment, including duration, and "OFF" and "discontinue"

options; and "stop and start" buttons)*, a resume infusion feature, and a remove pump*

feature.

33.   As per claim 4, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

    --*the second functional feature set comprises at least one of a patient*

management feature, an item management feature, a facility management feature, a

messaging feature, an alarms/alerts feature (see: De La Huerga, paragraphs 211, 243,

is met by alert activator, and indicator activation), *a billing interface feature, a formulary*

interface feature, a lab results interface feature, an inventory tracking feature, a clinician

administration feature, an order entry feature, a pharmacy feature, a user interface

feature, a user interface and clinician association feature, a volumetric infusion pump

feature, and a syringe pump feature.

34.   As per claim 5, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the first database comprises at least one of pump data (Fig. 18)(see: De La

Huerga, paragraph 151, 152, 167, 208, 210, 273, and 322, is met by delivery

parameters), *pump channel data, pump sub-channel data, order data, clinician data,*

patient data, user interface data, medical device data, hub data, titration data,

comparison data, alarm data, escalation data, hub alarm data, pump alarm data,

channel alarm data, and alarm history data.

35.   As per claim 6, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

      --the second database comprises at least one of patient management data (Fig.

26, ele. 260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200,

is met by memory with stored patient ID), *item management data, facility management*

data, messaging data, alarms/alerts data, inventory tracking data, a clinician

administration data, order entry data, user interface and clinician association data.

36.   As per claim 7, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--the first central computer is operably connected to the second computer

through at least one of a dedicated TCP/IP hard-wired connection, a high speed, low

latency virtual private network, and a public or shared infrastructure utilizing encryption

through a fiber optic connection, a microware connection, or a high speed wireless

connection (Fig. 26, ele. 100a, 100b, 255a, 255b, and 260)(see: De La Huerga,

paragraphs 149, 194, 195, and 273, is met by wireless connections).

37.   As per claim 8, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--the second central computer sends data from the second database to the first

central computer in a first standard protocol, and the first central computer sends the

data to the user interface in a second standard protocol (Fig. 17, ele. 104, 123, 124, and

255; Fig. 26, ele. 100a, 255a, and 260; and Fig. 26A, ele. 622)(see: De La Huerga,

paragraphs 145-151, 194, 195, and 211, the first protocol is met by communication

between the interface and the first computer, and the second protocol is met by the

plurality of protocols including: an Internet protocol, Bluetooth protocol, and IRDA

protocol).

38.   As per claim 9, De La Huerga teaches the invention as claimed, see discussion

of claim 1, and further teaches:

--the second central computer sends second data from the second database to

the first central computer, wherein the first central computer combines the second data

with first data from the first database with the second data, and wherein the first central

computer sends the combined fist and second data to the user interface for display on a

display of the user interface (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and 260; and Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149-151, 211, 285, and 289-291, is met additional patient information obtained from remote facility server and displayed on interface screen; is met by the controller activating an indicator, or alert displaying patent's name, on the interface via the infusion controller; and is met by altering infusion status parameters displayed on the user interface with data entered at the controller or infusion controller).

39.   As per claim 11, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

   --the first central computer receives second data from the second database in the second central computer for use in a validation procedure (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller).

40.   As per claim 13, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

   --the first central computer receives data from at least one of the user interface (see: De La Huerga, paragraph 290, is met by change of dose via the interface keypad) *and the medical device,*

   --and determines whether the received data is valid in order to enable the first central computer to perform a further step (see: De La Huerga, paragraph 159 and 290, is met by changes to delivery instructions using the interface allowed if verified by the infusion controller as acceptable).

41. As per claim 14, De La Huerga teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer sends operation data from at least one of the first database and the second database to the medical device for use in the operation of the medical device (see: De La Huerga, paragraph 149-151, is met by the infusion controller controlling the pump to infuse medications).

42. As per claim 15, De La Huerga teaches a method for operating a healthcare system in a care-giving facility having a medical device, a user interface, a first central computer securely connected to a second central computer having a second database, the method comprising the steps of:

--receiving medical data directly from a medical device (Fig. 26, ele. 830)(see: De La Huerga, paragraph 295 and 296, is met by monitoring device);

--receiving user data directly from a user interface (Fig. 26, ele. 264 and 266)(see: De La Huerga, paragraph 192, 193, 201, 207, 208, and 209, is met by interface including keyboard for to receive input from a controller user);

--receiving second data from a second database in a second central computer (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraph 259, 260, 271, and 320, is met by the server and its database from which data is provided to the receiving controller) *and from a secure connection* (Fig. 26, ele. 272; and Fig. 31, ele., 272)(see: De La Huerga, paragraph 89, 194, 195, 291, 300, and 320, is met by the network and network protocols);

--retrieving first data from a first database in a first central computer (Fig. 26A,

ele. 620 and 622)(see: De La Huerga, paragraph 192, 199, 200-206, is met by controller

memory storing patient and pump information, and associated processor able to retrieve

and send to the interface the stored information); *and,*

--utilizing a first functional feature set to process at least one of the first data and

the second data (see: De La Huerga, paragraph 259-260, 269-271, and 320, is met by

the controller upon receiving a prescription order accessing remaining components on

dispensed medication information, via a network, from a hospital computer system and

database).

It has bee shown above that De La Huerga also teaches that the first database:

is a subset of the second database, (see: De La Huerga, paragraph 243, is met by

server that archives all standing infusion orders); however, addressing the alternative

situation in which De La Huerga does not teach that the first database: *is a subset of the*

second database, Christensen teaches a first and second database that are able to

work in a coordinated manner in which the second database reflects or contains the

same information as the first database (see: Christensen, paragraph 61). It would have

been obvious to one of ordinary skill in the art at the time the invention was made to

combine the teachings of De La Huerga and Christensen. The well known elements

described are merely a combination of old elements, and in the combination, each

element merely would have performed the same function as it did separately, and one

of ordinary skill in the art would have recognized that the results of the combination

were predictable.

43.   As per claim 16, De La Huerga teaches the invention as claimed, see discussion

of claim 15, and further teaches:

--*the medical device and the user interface do not communicate directly with the*

second central computer (Fig. 26, ele. 630, 632, 272, and 260; and Fig. 26, ele. 830,

255c, 260, 270, and 272, is met by configuration of the controller, medical device, the

interface, and the database and server)(see: De La Huerga, paragraph 259-260, 269-

271, 295, 296, and 320).

44.   As per claim 17, De La Huerga teaches the invention as claimed, see discussion

of claim 15, and further teaches:

--*providing for sending the second data to the user interface from the first central*

computer (Fig. 26, ele. 630, 632, 272, and 260; and Fig. 26, ele. 830, 255c, 260, 270,

and 272, is met by configuration of the controller, medical device, the interface, and the

database and server)(see: De La Huerga, paragraph 259-260, 269-271, 295, 296, and

320, is met by the controller upon receiving a prescription order accessing with the

controller interface the remaining components on dispensed medication information, via

a network, from a hospital computer system and database).

45.   As per claim 18, De La Huerga teaches a healthcare system for a care-giving

facility, comprising:

--*a medical device* (Fig. 17, ele. 108; and Fig. 26, ele. 108a, 108b, 108c, and

108d)(see: De La Huerga, paragraphs 187, is met by IV pumps);

--*a user interface* (Fig. 17, ele. 106 and 123)(see: De La Huerga, paragraph 145,

is met by display, keyboard, and mouse);

--a central validation computer having a validation database (Fig. 17, ele 103,

104, and 105; and Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 145,

151, and 152, is met by infusion controller, its processor and memory) *and a first*

functional feature set associated with the data and functions related to the medical

device and the user interface (Fig. 18)(see: De La Huerga, paragraph 151, 152, and

167, is met by delivery parameters), *wherein the medical device and user interface*

communicate directly and securely with the central validation computer (see: De La

Huerga, paragraph 145, 146, 147, and 149);

--a second central computer having a second database (Fig. 26, ele. 260; and

Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met

by controller and memory) *and a second functional feature set* (see: De La Huerga,

paragraphs 211, 243, is met by alert activator, and indicator activation), *wherein the*

user interface can receive data from the second database relating to the second

functional feature set of the second central computer through the central validation

computer (Fig. 17, ele. 104, 123, 124, and 255; Fig. 26, ele. 100a, 255a, and 260; and

Fig. 26A, ele. 622)(see: De La Huerga, paragraph 149, 151, and 211, is met by the

controller activating an indicator via the infusion controller).

It has been shown above that De La Huerga also teaches: *wherein the validation*

database is a subset of the second database, (see: De La Huerga, paragraph 243, is

met by server that archives all standing infusion orders); however, addressing the

alternative situation in which De La Huerga does not teach: *wherein the validation*

database is a subset of the second database, Christensen teaches a first and second

database that are able to work in a coordinated manner in which the second database

reflects or contains the same information as the first database (see: Christensen,

paragraph 61). It would have been obvious to one of ordinary skill in the art at the time

the invention was made to combine the teachings of De La Huerga and Christensen.

The well known elements described are merely a combination of old elements, and in

the combination, each element merely would have performed the same function as it did

separately, and one of ordinary skill in the art would have recognized that the results of

the combination were predictable.

46.   As per claim 19, De La Huerga teaches the invention as claimed, see discussion

of claim 18, and further teaches:

     --the central validation computer is securely connected to the second computer

computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 149, 195, and

273, is met by the various networks).

47.   As per claim 20, De La Huerga teaches the invention as claimed, see discussion

of claim 18, and further teaches:

     --the medical device and the user interface do not communicate directly with the

second central computer (Fig. 17, ele. 100, 104, 123, 124, and 255; and Fig. 26, ele.

100a, 255a, and 260, is met by configuration of the controller, infusion controller, and

the interface)(see: De La Huerga, paragraph 149, 151, and 211, is met by the controller

activating an indicator via the infusion controller).

48.   As per claim 21, De La Huerga teaches the invention as claimed, see discussion

of claim 18, and further teaches:

--the central validation computer receives second data from the second database

in the second central computer for use in a validation procedure performed by the

central validation computer (see: De La Huerga, paragraph 219, is met by infusion

controller validating physician identification with information received from the

controller).

49.   As per claim 23, De La Huerga teaches the invention as claimed, see discussion

of claim 21, and further teaches:

--central validation computer receives first data from at least one of the user

interface (see: De La Huerga, paragraph 290, is met by manual change dose via the

interface keypad) *and the medical device, and*

--wherein the validation procedure comprises the step of determining whether the

first data matches the second data (see: De La Huerga, paragraph 159 and 290, is met

by changes to delivery instructions using the interface allowed if verified by the infusion

controller as acceptable).

50.   **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent Application Publication 2003/0038392 to De La Huerga in view of Examiner's

Official Notice.

51.   As per claim 10, De La Huerga teaches the invention substantially as claimed,

see discussion of claim 1, and further teaches:

--a plurality of wireless access points through which the user interface

communicate with the first central computer (see: De La Huerga, paragraph 194, 195,

and 273).

De La Huerga anticipates many wireless embodiments (see: De La Huerga, paragraph 89) but does not specifically teach that the connection between the medical device and the first computer is wireless, instead only that they are "linked" (see: De La Huerga, paragraph 149); however, the Examiner takes official notice that connecting medical devices to computers wirelessly was common, old, and well known to someone of ordinary skill in the art at the time the invention was made. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga and Official Notice. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

52.   **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2003/0084024 to Christensen further in view of Examiner's Official Notice.

53.   As per claim 10, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--*a plurality of wireless access points through which the user interface communicate with the first central computer* (see: De La Huerga, paragraph 194, 195, and 273).

De La Huerga anticipates many wireless embodiments (see: De La Huerga, paragraph 89) but does not specifically teach that the connection between the medical

device and the first computer is wireless, instead only that they are "linked" (see: De La

Huerga, paragraph 149); however, the Examiner takes official notice that connecting

medical devices to computers wirelessly was common, old, and well known to someone

of ordinary skill in the art at the time the invention was made. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to combine

the teachings of De La Huerga, Christensen, and Official Notice. The well known

elements described are merely a combination of old elements, and in the combination,

each element merely would have performed the same function as it did separately, and

one of ordinary skill in the art would have recognized that the results of the combination

were predictable.

54.   **Claim 12, 22, 26, and 28** are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga

in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

55.   As per claim 12, De La Huerga teaches the invention substantially as claimed,

see discussion of claim 11, but fails to specifically teach:

> *--the validation procedure comprises the steps of receiving an XML document*
> *and determining whether the data expected to be received from the XML document is*
> *received.*

However, such receiving and determining of XML documents is well known in the

art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been

obvious to one of ordinary skill in the art at the time the invention was made to combine

the teachings of De La Huerga and Gayle et al. The well known elements described are

merely a combination of old elements, and in the combination, each element merely

would have performed the same function as it did separately, and one of ordinary skill in

the art would have recognized that the results of the combination were predictable.

56.   As per claim 22, De La Huerga teaches the invention substantially as claimed,

see discussion of claim 21, but fails to specifically teach:

   --the validation procedure comprises the steps of receiving an XML document

and determining whether the data expected to be received from the XML document is

received.

   However, such receiving and determining of XML documents is well known in the

art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been

obvious to one of ordinary skill in the art at the time the invention was made to combine

the teachings of De La Huerga and Gayle et al. The well known elements described are

merely a combination of old elements, and in the combination, each element merely

would have performed the same function as it did separately, and one of ordinary skill in

the art would have recognized that the results of the combination were predictable.

57.   As per claim 26, De La Huerga teaches the invention substantially as claimed,

see discussion of claim 25, but fails to specifically teach:

   --the first and second operating systems are separated by a fire wall.

   However, such firewalls are well known in the art as evidenced by Gayle et al.

(Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37). It would have been obvious to

one of ordinary skill in the art at the time the invention was made to combine the

teachings of De La Huerga and Gayle et al. The well known elements described are

merely a combination of old elements, and in the combination, each element merely

would have performed the same function as it did separately, and one of ordinary skill in

the art would have recognized that the results of the combination were predictable.

58.   As per claim 28, De La Huerga teaches the invention substantially as claimed,

see discussion of claim 24, and further teaches:

--*the central computer comprises a first server* (Fig. 26A, ele. 620 and 622)(see:

De La Huerga, paragraph 192, 199, 200-206, is met by controller processor and

memory) *and a second separate server* (Fig. 31, ele. 630 and 632)(see: De La Huerga,

paragraph 259, 260, 271, and 320, is met by the server and its database), *wherein the*

central validation portion of the central computer resides in the first server (Fig. 26)(see:

De La Huerga, paragraph 200-206, 210, 273, and 296, is met by network validation

protocols such as Bluetooth among others, and further validates through polling, pump

and controller address checks, and ID checks), *and wherein the second non-validation*

portion of the central computer resides on the second server (Fig. 31, ele. 630 and

632)(see: De La Huerga, paragraph 259, 260, 271, and 320, is met by the server and

its database from which data is provided to the receiving controller).

Fails to specifically teach:

--*the first and second servers being separated by a fire wall*

However, such firewalls are well known in the art as evidenced by Gayle et al.

(Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37). It would have been obvious to

one of ordinary skill in the art at the time the invention was made to combine the

teachings of De La Huerga and Gayle et al. The well known elements described are

merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

59.   **Claim 12 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2003/0084024 to Christensen further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

60.   As per claim 12, De La Huerga teaches the invention substantially as claimed, see discussion of claim 11, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Christensen, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

61.   As per claim 22, De La Huerga teaches the invention substantially as claimed, see discussion of claim 21, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Christensen, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

62.   **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of legal precedent as cited in the MPEP chapter 2144.04 parts B (Making Integral).

63.   As per claim 27, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, but fails to teach:

--the central computer is a single server.

However, that the central computer is composed of a single server instead of a plurality of servers is merely a matter of obvious design choice (see: MPEP, Chapter 2144.04, part B, Making Integral). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Christensen, and the MPEP. The well known elements described are merely a

combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

Response to Arguments

64.   Applicant's arguments from the response filed on 12/23/2008 have been fully considered and will be addressed below in the order in which they appeared.

65.   In the remarks, Applicant argues in substance that (1) "De La Huerga fails to teach a first computer having a database containing a subset of a second computer's database"; that (2) "De La Huerga also fails to teach the second central computer sending data from the second database to the first central computer, and the first central computer sending data to the user interface as required by dependent Claims 8 and 9. Instead, De La Huerga teaches a single controller for imparting all instructions and performing all validations necessary, as described in detail above. The Office Action asserts that De La Huerga meets the data communication between first and second central computers by communication between the interface and the first computer. However, Claims 8 and 9 do not recite interaction with the interface during the communication between first and second central computers"; that (3) "De La Huerga further fails to teach a system wherein the medical device and the user interface do not communicate directly with the second central computer as required by dependent Claims 16 and 20. Similarly, De La Huerga fails to disclose or suggest sending the second data (from the second central computer) to the user interface from the first central computer. Instead, Figure 26 of De La Huerga illustrates direct communication

between controller 260 and pump 100a and associated interface through

communication channel 255"; that (4) "Regarding independent Claim 24, De La Huerga

also fails to disclose or suggest a central validation portion of a central computer having

a validation portion of a database and a second non-validation portion of the central

computer having a second non-validation portion of the database, wherein the user

interface can receive data from the second non-validation portion of the database

through the central validation portion of the central compute"; that (5) "The Office Action

asserts that the controller serves as the central validation portion while the

server/database serves the non-validation portion. However, neither of these

components individually possesses both a validation and non-validation portion of the

component database"; and that (6) "Regarding the Official Notice, Applicants

respectfully traverse and do not agree that connecting medical devices to computers

wirelessly was common, old, and well known to someone of ordinary skill at the time the

invention was made. Applicants note that the Office Action does not include any

evidence to support the Official Notice".

66.   As per Applicant's argument that (1) "De La Huerga fails to teach a first computer

having a database containing a subset of a second computer's database", the Examiner

respectfully disagrees.

        Applicant's arguments with respect to the limitation included upon amendment

have been considered but are moot in view of the new ground(s) of rejection.

67.   As per Applicant's argument that (2) "De La Huerga also fails to teach the second

central computer sending data from the second database to the first central computer,

and the first central computer sending data to the user interface as required by

dependent Claims 8 and 9. Instead, De La Huerga teaches a single controller for

imparting all instructions and performing all validations necessary, as described in detail

above. The Office Action asserts that De La Huerga meets the data communication

between first and second central computers by communication between the interface

and the first computer. However, Claims 8 and 9 do not recite interaction with the

interface during the communication between first and second central computers", the

Examiner respectfully disagrees.

Applicant's arguments are not persuasive. In Fig. 26, De La Huerga teaches two

controllers, or computers, that interact as claimed by Applicant. The first computer

controller is an "infusion controller", which, as cited to Applicant, includes an interface,

processor, and memory. The infusion controller is connected directly to the IV pump.

The infusion controller is also connected to a second controller that also contains a

processor and memory and is in two-way communication with the first infusion

controller. Therefore, as Applicant has claimed, De La Huerga teaches a medical device

(the pump), a user interface (there is an interface on both controllers), a first computer

(infusion controller), and a second computer (the second controller). They are

configured such that any communication to the medical device is routed through the

infusion controller, and such that direct communication from the second controller to the

medical device is not possible. The protocol limitations of claim 8 are met by the

communication between the devices by a plurality of protocols, including: an Internet

protocol, BLUETOOTH protocol, and IRDA protocol. The combining of data elements in

claim 9, is met with a plurality of examples, including: additional patient information

obtained from a remote facility server and displayed on interface screen; the controller

activating an indicator, or alert displaying patient's name, on the interface via the

infusion controller; and by altering infusion status parameters displayed on the user

interface with data entered at the controller or infusion controller.

Note: The Examiner would like to point out that Applicant is relying heavily on

aspects of design choice in the claims. That the healthcare system is composed of two

computers instead of, say, a single computer, is merely a matter of obvious design

choice (see: MPEP, Chapter 2144.04, part B, Making Integral, and part C, Making

Separable). While prior art was found that meets Applicant's elements of design choice,

a single computer that performs the same functions and returns the same results as

Applicant's two-computer setup would still be successful in meeting Applicant's claims.

68.   As per Applicant's argument that (3) "De La Huerga further fails to teach a

system wherein the medical device and the user interface do not communicate directly

with the second central computer as required by dependent Claims 16 and 20. Similarly,

De La Huerga fails to disclose or suggest sending the second data (from the second

central computer) to the user interface from the first central computer. Instead, Figure

26 of De La Huerga illustrates direct communication between controller 260 and pump

100a and associated interface through communication channel 255", the Examiner

respectfully disagrees.

Applicant's arguments are not persuasive. This argument is substantially the

same as argument (2) covered above, but is further covered here: The user interface

connected to the infusion controller does not communicate directly with the second

controller - it communicates to the second controller only through the infusion controller.

Paragraphs 149-151 of De La Huerga show that through the interface connected to the

infusion controller, the infusion controller can link to other computers and storage

devices. In paragraph 149, in reference to Fig. 17, De La Huerga states that the infusion

controller "[p]rocessor 104 is linked to each of display 123" in addition to being "linked to

communication channel such as an intranet or the Internet for communication with other

facility or remote computing and storage devices", and in paragraph 150, the infusion

controller "controls each pump unit 108 to infuse intravenous fluids to a patient from IV

bags", and in paragraph 151, teaches accessing patient information either directly from

the memory device "or additional patient information obtained via communication

channel 255 and a remote facility server/database." In this way, De La Huerga teaches

an interface, connected directly to an infusion controller, which is connected to a

medication pump and another controller, database or server. Information from the other

controller, database, or server can be accessed through the infusion controller by the

interface and through the interface the medication pump can be controlled.

69.   As per Applicant's argument that (4) "Regarding independent Claim 24, De La

Huerga also fails to disclose or suggest a central validation portion of a central

computer having a validation portion of a database and a second non-validation portion

of the central computer having a second non-validation portion of the database, wherein

the user interface can receive data from the second non-validation portion of the

database through the central validation portion of the central compute", the Examiner

respectfully disagrees.

Applicant's arguments are not persuasive. Claim 24 was interpreted in an

alternate way than the similar independent claims that precede it, in order to show how

broadly the claims were written. In this interpretation of De La Huerga teaches, the

infusion controller and the medical device were considered a single device, i.e., the

entire apparatus including the pump and infusion controller (computer with processor,

interface, and memory) was considered the medical device, though, medical device is a

broad term that could refer to almost anything in a medical environment. In this

interpretation, the user interface is met by the interface including the keyboard for

receiving input from a controller user (Fig. 26, ele. 264 and 266). The central computer

in this interpretation was the controller, i.e., second computer in the first interpretation;

again, because in this interpretation the pump and the infusion controller computer are

considered a single medical device. The central validation portion of a database was

met by the network validation protocols, and validation through polling, pump and

controller address checks, and ID checks. The functional feature set with its relation to

the interface and medical device was met by the controller checking medical monitors

and pump status checks, and alerting pertaining to delivery parameters. The second

non-validation portion of the central computer is met by an outside server and its

database from which data is provided to the receiving controller. The functional feature

set of the second non-validation portion is met by the controller, upon receiving a

prescription order, accessing remaining components on dispensed medication

information, via a network, from a hospital computer system and database.

70.   As per Applicant's argument that (5) "The Office Action asserts that the controller

serves as the central validation portion while the server/database serves the non-

validation portion. However, neither of these components individually possesses both a

validation and non-validation portion of the component database", the Examiner

respectfully disagrees.

Applicant's arguments are not persuasive. This argument is substantially the

same as argument (4) covered above, but is further covered here: The argument

substantially concerns the differentiation between a validation and non-validation portion

of a database. The term "validation" is very broad. De La Huerga meets the limitation of

validation by teachings "process of determining the status of medicants begin delivered

to patient", further validation is taught "to identify all pumps" and to "obtain current pump

unit status information". Furthermore, for validation purposes, "patient ID", "controller

ID", and "system address" are provided (see: De La Huerga, paragraph 201). As per the

non-validation portion of the database is the delivery parameters comparison where the

server "determines if the difference between dispensed delivery information and at least

one of the currently prescribed medicants is only with respect to delivery parameters"

(see: De La Huerga, paragraph 259).

71.   As per Applicant's argument that (6) "Regarding the Official Notice, Applicants

respectfully traverse and do not agree that connecting medical devices to computers

wirelessly was common, old, and well known to someone of ordinary skill at the time the

invention was made. Applicants note that the Office Action does not include any

evidence to support the Official Notice", the Examiner respectfully disagrees.

Applicant has attempted to challenge the Examiner's taking of Official Notice in

the Office Action mailed 12/23/2008. There are minimum requirements for a challenge

to Official Notice:

(a)   In general, a challenge, to be proper, must contain adequate information

or arguments so that *on its face* it creates a reasonable doubt regarding the

circumstances justifying the Official Notice.

(b)   Applicants must seasonably traverse (challenge) the taking of Official

Notice as soon as practicable, meaning the next response following an Office Action. If

an applicant fails to seasonably traverse the Official Notice during examination, his right

to challenge the Official Notice is waived.

Applicant has not provided adequate information or arguments so that *on its face*

it creates a reasonable doubt regarding the circumstances justifying the Official Notice.

Therefore, the presentation of a reference to substantiate the Official Notice is not

deemed necessary. The Examiner's taking of Official Notice has been maintained.

Bald statements such as, that Applicants "do not agree that connecting medical

devices to computers wirelessly was common, old, and well known to someone of

ordinary skill at the time the invention was made", are not adequate and do not shift the

burden to the Examiner to provide evidence in support of the Official Notice.

However, despite these deficiencies, the Examiner has found evidence "that

connecting medical devices to computer wirelessly was common, old, and well known to

someone or ordinary skill at the time the invention was made". In U.S. Patent 6,790,198

to White, White teaches "[a] wireless communication system from an IV medication

infusion pump to a hospital information management system (HIMS)" (see: White,

abstract).

Conclusion

72.   Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

73.   A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

74.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ROBERT SOREY whose telephone number is

(571)270-3606. The examiner can normally be reached on Monday through Friday,

8:30AM to 5:00PM (EST).

75.   If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Christopher Gilligan can be reached on (571)272-6770. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

76.   Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3626
March 9, 2009

/Robert Morgan/
Primary Examiner, Art Unit 3626